Guidance for Conflicts Disclosure in Informed Consent

Conflicts of interest exist when an investigator or the institution has financial or personal relationships that may compromise or present the appearance of compromising an individual’s, group’s, or institution’s judgment in conducting, reviewing, or reporting research. These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflicts of interest. A fully informed consent is one in which all related financial interests are disclosed.

To facilitate appropriate disclosure of potential conflicts of interest in the informed consent document, the following suggested language is provided. It is not mandatory to use these specific provisions. Language should be modified to fit the specific facts and circumstances.

This study is paid for by [name of sponsor] which [has no financial interest in its outcome] (or) [owns the [drug] (or) [device] being tested and thus has a financial interest in the outcome of the study]. Payments are made to Weill Cornell Medical College (WCMC) and the funds are used to cover the expenses of the study and related academic and research activities of the institution. [The investigators and the Weill Cornell Medical College do not have any financial interest in the outcome of the study] (or) [insert disclosure of potential conflict(s) of interest by investigator(s) and/or institution(s); using such statements as the following:

1. The investigator, Dr. ______________ (full name), owns equity (stock) of the company which is paying for this research.

2. The investigator, Dr. ______________ (full name), personally receives consulting or other payments from the company which is paying for the study.

3. The Cornell Research Foundation, a fully owned subsidiary of Cornell University, owns equity (stock) of the company which is paying for this study.

4. The investigator, Dr. __________, is an inventor of [the drug, compound, device, etc.], for which a patent may be filed by the institution. If the patent is pursued, based on data from this and other research, royalties and other compensation may be received by the institution and the investigator. Thus, WCMC and the investigator have a financial interest in the outcome of this study.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the investigator, Dr. ______________.

Guidance for Conflicts Disclosure in Publications and Presentations

Financial and/or Intellectual property interests must also be disclosed in all related publications, presentations, and press releases.

Questions about the Weill Cornell Medical College Study Specific Financial Disclosure Form can be directed to the Division of Research Integrity, Conflicts Management Office at 212-821-0647 or conflicts@med.cornell.edu